

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED

JAN 4 - 2002

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Adverse
GREGORY (08/311,665),
Junior Party,

v.

Favorable
TSUI (08/123,864),
Senior Party. *S. J. Thomas 16c3*

Interference No. **103,882**

Favorable
GREGORY (08/087,132),
Junior Party, *✓ wet*

v.

Victor Adverse
COLLINS (5,240,846),
Junior Party, *07/584 275 S. J. Thomas 9200 mailed*

v.

Adverse
TSUI (08/252,778),
Senior Party, *✓ NO CT*

Interference No. **103,933**

Adverse
GREGORY (08/470,534),
Junior Party, *1c Ab N*

v.

Adverse
RIORDAN (5,543,399),
Junior Party, *16c3 3rd fl. 08/290933 W. Degan mailed*

v.

Favorable
TSUI (08/469,630),
Senior Party, *NO CT*

Interference No. **104,228**

CONSOLIDATED JUDGMENT

08/087132

ODR DNA

*Allow
cl 13-18
with*

wet cl 226.227

silva

Before SCHAFER, TORCZON, and SPIEGEL, Administrative Patent Judges.

TORCZON, Administrative Patent Judge.

JUDGMENT
(PURSUANT TO 37 C.F.R. § 1.658)

INTRODUCTION

These interferences are decided on the basis of motions attacking accorded benefit as provided in each interference in an interlocutory order dated 6 July 2001. No party challenged that order at the final hearing. A final hearing on motions was held on 4 December 2001. Bruce Collins argued for Gregory. Debra Shetka argued for Tsui.¹ The other parties did not present arguments apart from those made by Ms. Shetka.

The interferences all relate to the cystic fibrosis transmembrane receptor (CFTR), a protein that, when defective, is a cause of cystic fibrosis in humans.

FACTS

1. For each of its involved applications, the earliest benefit accorded to Tsui is its 07/401,609 (609) application, filed 31 August 1989 (abandoned).
2. Collins' involved patent also claims, and was accorded, the benefit of the Tsui 609 application for the purposes of interference priority.
3. Riordan's involved patent also claims, and was accorded, the benefit of the Tsui 609 application for the purposes of interference priority.
4. For each of its involved applicants, the earliest benefit accorded to Gregory is its 07/488,307 (307) application, filed 5 March 1990 (abandoned).

¹ Pronounced "Choi".

5. In the 933 interference, Gregory was also accorded the benefit of its 07/589,295 (295) application, filed 27 September 1990 (abandoned), which is a continuation-in-part of the 307 application.

6. Gregory has moved to deny Tsui the benefit of the 609 application.² Tsui has moved, contingent on the grant of Gregory's motion, to attack Gregory's accorded benefit.

7. The sole count in the 103,882 (882) interference is (882 Paper No. 1 at 3):

Nucleic Acid encoding cystic fibrosis transmembrane conductance regulator (CFTR).

8. The sole count in the 103,933 (933) interference is (933 Paper No. 1 at 2):

A recombinant vector for a target cell, the vector comprising:

a) a DNA regulatory element, and

b) a DNA sequence which encodes the cystic fibrosis transmembrane regulator protein, said DNA sequence operably linked to the DNA regulatory element and capable when so linked of expression in the target cell *in vitro* or *in vivo*.

9. The sole count in the 104,228 (228) interference is (228 Paper No. 1 at 4):

Isolated and purified cystic fibrosis transmembrane conductance regulator (CFTR) protein.

² Gregory also attacked Tsui's accorded benefit to two earlier parent applications of the 609 application, but if Tsui is entitled to the benefit of the 609 application, then Tsui would still be senior party, which is sufficient for Gregory to lose. Conversely, if Tsui is not entitled to the benefit of its 609 application, then the earlier Tsui parent applications could not serve as constructive reductions in practice due to the break in continuity and thus Tsui would not be entitled to their benefit. *Cf. In re Costello*, 717 F.2d 1346, 1350, 219 USPQ 389, 391 (Fed. Cir. 1983) (abandonment resulting in a break in continuity strips earlier application of status as constructive reduction to practice). At the hearing, both counsel agreed that the focus was properly on Tsui's 609 application.

10. Gregory urges that Tsui failed to provide a written description of the manner and process of making the subject matter of the counts.³
11. Gregory acknowledges that it is sufficient, for the purposes of interference priority benefit, to have disclosed and enabled a single embodiment within the scope of the count (e.g., 882 Paper No. 127⁴ at 13-14).
12. Gregory's argument with regard to the 882 count is that Tsui's 609 application does not disclose the manner of making of any "DNA" within the scope of the count.
13. The 882 count is directed to a nucleic acid encoding the CFTR protein.
14. Gregory's argument with regard to the 933 count is that Tsui's 609 application does not disclose the manner of making the "DNA component" of the scope of the count.
15. The 933 count is directed to a recombinant vector for a target cell where the vector contains regulatory DNA operably linked to CFTR DNA such that the target cell will express CFTR protein.
16. Gregory's argument with regard to the 228 count is that Tsui's 609 application does not disclose the manner of making the "DNA" for encoding the protein of the count.
17. The 228 count is directed to the CFTR protein.

³ The parties debated whether 35 U.S.C. 112[1] requires a written description of how to make the subject matter at issue. While we agree with Gregory that the statute literally requires "a written description...of the manner and process of making" the contested subject matter, that fact is not dispositive since the statute further states that the description need only be "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...." See Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941, 15 USPQ2d 1321, 1329 (Fed. Cir. 1990) (explaining that the focus is on whether, starting with the disclosure, one skilled in the art could have made invention without resort to undue experimentation). As the Northern Telecom opinion noted, the disclosure need not be "a production specification." Id.

⁴ Gregory Preliminary Motion 1 (To Deny Benefit).

The nucleic acid and protein counts

18. DNA is deoxyribonucleic acid, a kind of nucleic acid.
19. RNA is ribonucleic acid, a kind of nucleic acid.
20. cDNA is complementary DNA, a kind of nucleic acid.
21. In all of Gregory's motions to deny benefit, the focus is on Tsui's alleged inability to produce cDNA capable of encoding CFTR in E. coli host bacteria until after Gregory's earliest accorded effective filing date.
22. Tsui discloses making CFTR protein by injecting RNA into Xenopus oocytes⁵ (1042 at 101:23-25).⁶
23. Tsui also discloses the isolation of CFTR protein from the cell membrane fraction of cultured colonic carcinoma cell of the T84 line (1042 at 75:5-76:9). This method does not appear to rely on an isolated nucleic acid sequence for recovery of CFTR protein.
24. It is not apparent from Gregory's motions why the disclosure of non-bacterial protein expression systems, as well as isolation for the carcinoma cell line, is not adequate to instruct one skilled in the art on the manner of making, isolating, and purifying the CFTR protein. Gregory does argue that much of the disclosure appears to be "prophetic", that is, an explanation of what could be done as opposed to what had been done. That characterization appears to be apt for the alternate expression systems.

⁵ Egg cells of the African clawed frog, X. laevis. Frogs are eukaryotes, not bacteria.

⁶ Tsui exhibits are numbered in the one thousands in all three cases. Tsui exhibit 1042 is the disclosure of Tsui's 609 application. "101:23-25" means page 101, lines 23-25.

25. Tsui points to its isolation of an approximately 250 kb⁷ gene for encoding CFTR protein on a 380 kb Sal I restriction fragment, that is a fragment of genomic DNA separated from its surrounding DNA using the Sal I restriction enzyme (1042 at 26:6-26). The process for obtaining the Sal I fragment is also disclosed (1042 at 24:27-25:23).

26. Tsui disclosed isolation of 6.5 kb RNA from T84 cells that hybridizes with a cDNA probe for CFTR nucleic acids, with similar results for cells from specified tissues, especially those most affect by cystic fibrosis pathologies (1042 at 40:1-41:30).

27. It is not apparent from Gregory's motions why Tsui's disclosure of the isolation of genomic DNA and mRNA for encoding the CFTR protein is not sufficient enabling disclosure of isolation of a nucleic acid encoding CFTR protein.

The vector count

28. The 933 vector count requires the use of DNA, which can include both genomic DNA and cDNA, but not RNA.

29. Tsui has not pointed to any support for a vector using genomic DNA.

30. Tsui does point to various non-bacterial expression systems that may be transfected with CFTR cDNA and specified, known promoters (1042 at 96:9-31).

31. Gregory provides no reason to believe that Tsui's disclosed non-bacterial expression systems could not be transfected with a CFTR cDNA, provided the cDNA was available.

⁷ Kilobase, or one thousand nucleic acid monomers.

32. Tsui points to its possession and deposit of three cDNA clones that collectively span the entire CFTR DNA sequence. Tsui does not, however, disclose a manner of making a continuous CFTR cDNA. Tsui does not explain how it would use separate overlapping clones to make a vector; rather, it appears to presume the availability of the full-length cDNA.

33. The 609 specification discloses many examples of errors creeping into the making of cDNA clones no matter what approach Tsui tried (1042 at 30:16-29, 30:35-31:1, 31:9-18, 32:12-13, and 36:29-35).

34. The 609 application shows that Tsui considered various causes for cloning problems (1042 at 20:14-24 and 33:25-28), but Tsui's opposition does not explain how the disclosure itself would have pointed one skilled in the art to latent E. coli toxicity as the cause or silent mutations in the cDNA as a likely solution.

35. The science journal Nature published a Gregory article in September 1990, more than one year after the filing date of the 609 application, identifying bacterial toxicity of full-length CFTR cDNA as a problem and providing a solution (using a low copy number vector) (4016).⁸

36. We take administrative notice that Nature indicates that it is a highly selective journal.⁹

⁸ R.J. Gregory et al., "Expression and characterization of the cystic fibrosis transmembrane conductance regulator", 347 Nature 382, 382 (27 Sep. 1990). Gregory exhibits are all numbered in the four thousands.

⁹ http://www.nature.com/nature/submit/get_published/index.html (visited 19 Dec. 2001) (copy attached), stating, in part:

The criteria for publication of scientific papers in Nature are that they:

- report original scientific research (the main results and conclusions must not have been published or submitted elsewhere; see Guide to Authors)
- are of outstanding scientific importance

(continued...)

37. In April 1990, after the 609 application filing date, Tsui inventors indicated that they could not produce cDNA cloning vectors (4007¹⁰ at 44).

38. In October 1990, Tsui co-inventors Collins and Drumm indicated that conventional cloning methods (including using low copy number vectors) had failed to produce normal, full-length CFTR cDNA, but that small amounts of such cDNA could be produced by ligation of smaller clones (4006¹¹ at item 8).

39. Tsui's opposition does not explain how the 609 application would have directed one skilled in the art to try making the full-length cDNA from smaller clones.

40. In September 1990, after the filing date of the 609 application, the journal Cell published an article by several Tsui inventors that stated (4005¹² at 1227-28):

Early attempts to reconstitute a full-length CFTR cDNA from overlapping clones were uniformly unsuccessful. The exact cause of these difficulties remains to be defined, but we have data to show that prokaryotic transcription from internal CFTR cDNA sequences may result in the expression of a protein that is toxic to bacteria.

⁹ (...continued)

• are of interest to an interdisciplinary readership.

Papers published in Nature have an exceptionally wide impact, both among scientists and frequently among the general public.

¹⁰ Transcript, L.-C. Tsui et al. in The Identification of the CF (Cystic Fibrosis) Gene at 44 (L.-C. Tsui et al. eds. 1991) (Tsui noting protein expression problems; Tsui and Collins hypothesizing the problem to be cryptic promoters in the DNA; and Riordan explaining that related proteins are toxic to bacteria) (transcript apparently made 9-11 April 1991).

¹¹ M. Drumm et al., "The Full-Length CFTR cDNA Is Toxic In Bacterial Hosts" in Pediatric Pulmonology, Supp. 5 at 189 (1990) (a report on a conference 3-6 October 1990).

¹² M.L. Drumm et al., "Correction of the Cystic Fibrosis Defect In Vitro by Retrovirus-Mediated Gene Transfer", 62 Cell 1227 (21 Sep. 1990).

41. We take administrative notice that Cell indicates that it is a highly selective journal.¹³

42. The Cell article explains how the introduction of three silent¹⁴ mutations cured the problem of toxicity in E. coli.

43. In its opposition, Tsui provides a host of strategies for solving the problems with producing full-length CFTR cDNA in E. coli (Paper No. 145 at 9-10).

44. Tsui provided the declaration¹⁵ of Peter N. Ray, an employee of the Hospital for Sick Children, which we understand to be affiliated with a Tsui real party-in-interest, HSC Research Development Corporation.

45. Dr. Ray points (1001', ¶3) to the Tsui disclosure that in screening an E. coli based library of cDNA clones, fewer clones were detected than expected, leading the inventors to state "it seemed probable that the clones that contained aberrant structures were preferentially retained while the proper clones were lost during propagation" (1042 at 31:9-15). From this, Dr. Ray concludes that one skilled in the art would have recognized the problem of E. coli host cell incompatibility.

46. Dr. Ray further notes (1001', ¶4) that Tsui identifies methods of propagating unstable DNA (1042 at 20:14-24).

¹³ <http://www.cell.com/misc/authors.shtml> (visited 19 Dec. 2001) (copy attached), stating, in part: *Cell* publishes reports of novel results in any area of experimental biology. The work should be not only of unusual significance within its field but also of interest to researchers outside the immediate area.

¹⁴ Silent in the sense that changes in the nucleotide did not change the amino acid that was encoded.

¹⁵ "Tsui Declaration Exhibit 1001" (1001). This choice of numbering is unfortunate since there are now two Tsui exhibits numbered 1001. See 933 Paper No. 66, § 39, for guidance on numbering exhibits. Gregory moved to suppress this exhibit (Paper No. 161).

47. The discussion of propagating unstable DNA appears in an earlier part of the specification dealing with trying to obtain clones from genomic DNA, not with splicing partial clones together to make a full-length cDNA. Moreover, the discussion notes that it was not completely successful (1042 at 20:22-24):

Although the region near cosmid cW44 remains to be recovered, the region near X.6 was successfully rescued with these libraries.

48. The Drumm abstract (4006 at item 8) discussed above indicated that low-copy number E. coli vectors were not a solution because aberrant sequences still resulted. Moreover, the solution finally achieved by the Tsui inventors involved a very different approach: silent mutation of cryptic bacterial promoters in the CFTR cDNA (4005 at 1228).

49. While we credit Dr. Ray's testimony about what the 609 specification literally discloses and about the techniques available at the time the 609 application was filed, we do not accept his conclusions that one skilled in the art would have appreciated the source of the problem with propagating clones in E. coli. Indeed, the 609 specification discusses uses for the full-length cDNA without ever explicitly acknowledging any problem existed. Without an appreciation of the problem, any discussion of solutions to the problem is speculative at best.

50. Tsui bases its attack on Gregory's benefit on an alleged failure to disclose the best mode for making and using CFTR cDNA. In particular, Tsui alleges that Gregory knew or should have known that the cryptic E. coli promoter that Gregory identified in CFTR cDNA is the wrong (inactive) one and that Gregory failed to correct the problem subsequently when filing a continuation-in-part application.

DISCUSSION

- A. Gregory has not justified stripping Tsui of the benefit of the 609 application for the nucleic acid (882) and protein (228) counts

Gregory's attack on benefit focuses on Tsui's putative failure to disclose a manner of making an embodiment within the scope of the nucleic acid and protein count. More particularly, Gregory focuses on Tsui's putative failure to disclose a manner of making an embodiment using cDNA. Tsui argues, and its 609 application shows, that it disclosed enabling manners of making the nucleic acid and protein that do not depend on cDNA. Gregory's motion does not point to any reason why those alternate (non-cDNA) manners of making would not have been enabling.

Because of previous delays in the proceeding, the parties did not have an opportunity to file reply briefs, but Gregory's solution does not lie in a reply brief in any case. A movant has the obligation to make out a facially sufficient case in its motion. See Hillman v. Shyamala, 55 USPQ2d 1220 (BPAI 2000) (holding that a reply brief is not the place to fill in gaps in the initial motion). The examples Tsui points to were apparent in the 609 application when Gregory's motions were filed and should have been addressed at that time.

The Hillman decision also notes that disclosure for the purpose of according a constructive reduction to practice is similar to, but different from, disclosure for the purpose of attaining benefit under 35 U.S.C. 120. The principal difference lies in the practice that a constructive reduction to practice need describe only a single enabled embodiment within the

scope of the count.¹⁶ The reason for this difference is that neither party need be able to claim the entire scope of the count. Cf. 37 C.F.R. § 1.601(f) (last sentence describing a "phantom count"). Hence, the purpose of the constructive reduction to practice is to show an anticipation of the count within the meaning of 35 U.S.C. 102(g), not to show that the party is entitled to a claim with the full scope of the count. A claim is anticipated by disclosure in the prior art of a single embodiment within the scope of the claim, even if the claim encompasses more than that embodiment. Nevertheless, the embodiment must be adequately described and enabled to be counted as an anticipation. E.g., United States v. Adams, 383 U.S. 39, 50 (1966) (inoperable embodiments do not anticipate); In re Donohue, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985) ("well-settled" that an enabling disclosure is required for anticipation). A disclosure is presumed to be enabling, In re Cortright, 165 F.3d 1353, 1356-57, 49 USPQ2d 1464, 1466 (Fed. Cir. 1999), absent some clear indication to the contrary, id. at 1360, 49 USPQ2d at 1469. While it is true that Tsui relies heavily on "prophetic" examples, use of a prophetic example does not automatically make a disclosure non-enabling. The burden is on the movant to provide and explain evidence that the prophetic examples together with other parts of the disclosure are not enabling. Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984).

Factors to be considered in determining whether a disclosure would require undue experimentation ... include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art,

¹⁶ Gregory acknowledges as much. E.g., 882 Paper No. 127 at 13-14.

and (8) the breadth of the claims. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Not all of these factors need be reviewed to determine enablement. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999); Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts."). Gregory does not address any of these factors for either the genomic DNA and RNA disclosures or various non-cDNA protein recovery disclosures in the 609 specification. Consequently, Gregory has not met its burden of proof to show the 609 specification fails to enable a single embodiment within the scope of either the nucleic acid (882) count or the protein (228) count.

Tsui's contingent motions attacking Gregory's accorded benefit in the 882 and 228 interferences are moot since their contingency, the granting of Gregory's motion, has not occurred. Tsui's unopposed motion to amend its claims is also moot since it has prevailed and can address any necessary changes during further prosecution.

B. Gregory has shown that Tsui failed to provide an enabling disclosure
of an embodiment within the scope of the vector (993) count

Tsui has not pointed to a manner of making a vector within the scope of the 933 count without resort to CFTR cDNA. In this context, Gregory's attack on the putative enabling disclosure for such cDNA gains significance. Tsui does not identify any portion of the 609 specification that teaches a way to make full-length cDNA or a way to make a vector out of partial, overlapping cDNA clones.

In unpredictable arts, identification of the problem to be overcome may be a key to the solution, even though implementing the solution only requires routine skill. Once the problem with bacterial toxicity was deduced, several solutions may have immediately become plausible, but prior to that deduction, such solutions would have been just a few of a vast range of possible solutions to the unknown problem. At the time of filing, the 609 specification was inoperative as disclosed. A specification must provide more than an invitation to experiment. Enzo Biochem, at 1374, 52 USPQ2d at 1138. A considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance about how the experimentation should proceed in order to achieve the embodiment. PPG Indus. Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996); cf. Burroughs Wellcome Co. v. Barr Lab., Inc., 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994) (a research plan does not amount to conception). In the present case, the further efforts of the Tsui inventors (which were sufficiently important to merit publication in selective journals) and the lack of any recognition of the problem, much less guidance toward its solution, lead us to conclude that the experimentation necessary to render the Tsui 609 specification disclosure operable for the subject matter of the 933 vector count was more than simply routine.

If we again consider the 609 disclosure as a reference under § 102(g) against the 933 vector count, it fails the Adams test as a reference for lack of operability. If we turn, as Dr. Ray suggests, to other references to fill in the details, we are faced with a lack of motivation in the 609 disclosure to make the choices necessary to produce a solution. In essence, Dr. Ray invites us to apply with hindsight Tsui's post-filing appreciation of the problem and ability to find a

solution. To serve as a constructive reduction to practice, however, the disclosure had to be enabling as of its filing date. Cooper v. Goldfarb, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998).

At the time it was filed, Tsui's 609 application did not enable an embodiment within the scope of the 933 vector count.

C. Tsui has not established that Gregory is not entitled to the benefit of the 295 and 307 applications for the vector (933) count

Tsui's motion attacking Gregory's benefit proceeds on the theory that Gregory's 295 and 307 applications violate the best-mode requirement of 35 U.S.C. 112[1]. The problem with the attack is that it focuses on limitations of Gregory's claims. A motion attacking benefit accorded for the purpose of interference priority must provide its explanation in terms of the count. 37 C.F.R. § 1.637(g). The Court of Appeals for the Federal Circuit has repeatedly admonished against confusing claims and counts. E.g., In re Roemer, 258 F.3d 1303, 1307, 59 USPQ2d 1527, 1529 (Fed. Cir. 2001); In re Van Geuns, 988 F.2d 1181, 1184, 26 USPQ2d 1057, 1058-59 (Fed. Cir. 1993) (even when the count is identical to a claim). Yet in the present interferences, perhaps because both parties were limited to attacking benefit, both¹⁷ have tended to treat claims and counts as interchangeable.

In Cromlish v. D.Y., 57 USPQ2d 1318, 1319 (BPAI 2000), an Interference Trial Section panel noted, without resolving, the problem of relying on an alleged best-mode defect to attack

¹⁷ At the final hearing, in response to questions about the disconnect between the scope of the nucleic acid (882) count and the scope (cDNA) of Gregory's attack on Tsui's benefit, Gregory's counsel invited the panel to look at Tsui claims directed to cDNA. Fortunately in these interferences, both Gregory and Tsui have applications, so any actual § 112[1] problems that remain in the surviving claims of these applications can be examined in subsequent proceedings before the examiner.

interference priority benefit. Tsui addresses the problem by pointing to Bigham v. Godtfredsen, 857 F.2d 1415, 1417, 8 USPQ2d 1266, 1268 (Fed. Cir. 1988), and Hyatt v. Boone, 146 F.3d 1348, 1352, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998), for the proposition that the benefit application "must meet the requirements of 35 U.S.C. § 120 and 35 U.S.C. § 112, ¶1 for the subject matter of the count." Hyatt, 146 F.3d at 1352, 47 USPQ2d at 1130 (footnotes omitted). In Hyatt, best mode was not an issue before the court and, indeed, the cited paragraph finishes by discussing compliance with § 112[1] solely in terms of written description and enablement, in a case where only the written description issue was decided by the board. Similarly, Bigham is concerned with written description. Although a best-mode issue was raised in Bigham, the court insisted on treating the question as one of compliance with the written-description requirement. 857 F.2d at 1418, 8 USPQ2d at 1269. In short, the question before us--is there a best-mode requirement for a constructive reduction to practice--was not before the court in either case. Moreover, if we take the language of the cases literally--that a putative constructive reduction to practice must meet the all of the requirements of § 112[1], then those cases would be in conflict with other appellate precedent. Fontjin v. Okamoto, 518 F.2d 610, 620, 186 USPQ 97, 105 (CCPA 1975) (explaining that an application need only provide a single embodiment within the scope of the count, not support for the entire count); Tofe v. Winchell, 645 F.2d 58, 61, 209 USPQ 379, 382-83 (CCPA 1981) (best mode is not a priority consideration). Rather than find a conflict in appellate precedent, the wiser course is to recall that a judicial precedent cannot

be read apart from its facts.¹⁸ The facts of Bigham and Hyatt do not support Tsui's proposition that best-mode compliance is required in a constructive reduction to practice.

Since precedent does not squarely address the question, the next step is to determine whether it makes sense for best-mode compliance to be a requirement for a constructive reduction to practice. As the first section of this discussion notes, benefit for the purpose of priority is different from benefit for the purpose of patentability. A constructive reduction to practice by filing is essentially an anticipating reference under § 102(g) against the subject matter of the count. Other anticipating references need not disclose a best mode. It is not clear from Tsui's motion why a best-mode requirement should be engrafted onto constructive reductions to practice. The best-mode requirement creates a statutory bargain by which a patentee obtains the right to exclude others from practicing the claimed invention for a limited period in exchange for giving the public knowledge of the preferred embodiments for practicing the invention. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 962, 58 USPQ2d 1869, 1874 (Fed. Cir. 2001). Thus, fundamentally, the best-mode inquiry is directed to whether the applicant (Gregory) is entitled to its claimed subject matter. By contrast, an interference benefit determination is fundamentally about whether the other party (Tsui) is anticipated under § 102(g)(1). There is nothing inconsistent in a determination that Gregory was the first to invent the subject matter of the count (thus defeating Tsui's claim) but has forfeited its entitlement to a particular claim because of a best-mode violation.

¹⁸ The court in Hyatt faced a similar problem where the precedent used inconsistent (and seemingly divergent) tests for written description. The court declined to find a divergence and instead looked to the underlying policy of the statute to reconcile the apparent divergence. 146 F.3d at 1354, 47 USPQ2d at 1132.

Tsui argues that policy militates for a practice that enforces complete disclosure in the earliest accorded benefit application. Tsui advances two principal reasons for its position. The first, that it is the policy of the agency to discourage misconduct and to ensure the issuance of valid patents, is not persuasive. The argument is directed to claims and not to the relevant count. To the extent a problem really exists, it can be resolved in further prosecution. Had Tsui really felt such scruples about being a private attorney general with regard to Gregory's alleged best-mode violation, it could have filed a timely motion. It did not. The second argument, invoking In re Costello, 717 F.2d 1346, 219 USPQ 389 (Fed. Cir. 1983), requires further discussion.

Section 102(g) requires not only priority of invention, but also that the earlier inventor "had not abandoned, suppressed, or concealed" the invention. In Costello, the applicant had literally abandoned its earliest application and was now trying to overcome a rejection under 35 U.S.C. 102(e). Since Costello involves rejection of a claim and a lack of copendency under 35 U.S.C. 120, it is not really on point. Nevertheless, the court in Costello pointed to an earlier interference decision for the proposition that an abandoned application can only serve as evidence of conception, not as a constructive reduction to practice. 717 F.2d at 1350 n.13 & text, 219 USPQ at 391 n.13 & text, citing Carty v. Kellogg, 7 App. D.C. 542, 1896 Comm'r Dec. 188 (1896). Carty relies on an interference decision, Hien v. Pungs, 1894 Comm'r Dec. 92, 95, which in turn traces the rule to two earlier interference decisions, Beach v. Fowler, 1889 Comm'r Dec. 187, and Webster v. Sanford, 1888 Comm'r Dec. 92, both of which deal with abandonment of an application in the absence of any actual reduction to practice. Cf. Correge v. Murphy, 705 F.2d 1326, 1330, 217 USPQ 753, 756 (Fed. Cir. 1983) (explaining that failure to make the invention

publically known is the harm underlying abandonment). In both cases, the Commissioner affirmed a decision that the applicant had, for the purposes of a priority contest, abandoned the invention. Thus, the principle cited in Costello is that, in a priority contest, abandonment of an application is also an abandonment of that constructive reduction to practice for any purpose other than as evidence of conception because the applicant has "abandoned" the invention in the sense now codified in § 102(g). The applicant's cure is to resume efforts to make the invention publically known from a time prior to the conception of its opponent. All of this discussion of abandonment is remote, however, from a failure to disclose a best mode unless we make a leap from such failure to a holding of abandonment (a position that Tsui has not expressly advocated). A best-mode violation is not a failure to take any steps to make the invention known. Rather a best-mode violation is a holding back of information that is (by definition)¹⁹ not essential to the practice of the invention. We decline to equate a putative best-mode violation with abandonment for the purposes of § 102(g).

Tsui has not provided any other sufficient basis for stripping Gregory of the benefit of its earliest applications.

D. The status of the Collins and Riordan patents

Both Collins and Riordan rely on Tsui's 609 application for priority, but Tsui was designated senior party in their respective interferences. In the 933 interference, the

¹⁹ Otherwise, the violation would be a violation of the written-description requirement or the enablement requirement. E.g., Bigham, 857 F.2d at 1418, 8 USPQ2d at 1269 (no-mode is a written-description problem, not a best-mode problem).

609 application was held to be insufficient to be a constructive reduction to practice such that Gregory is now senior. Collins has provided no alternative basis for ruling in its favor.

In the 228 interference, the 609 application is sufficient, but Tsui is the senior party²⁰ and thus must prevail absent a compelling reason to the contrary. Riordan provided no such reason.

E. Other motions

Gregory's motion to suppress the Ray declaration is dismissed as moot since we do not rely on it to Gregory's detriment.

Gregory's motion to change inventorship (933 Paper No. 37) is dismissed as moot. Gregory can fix any remaining problem during further ex parte proceedings. There is no pending motion for invalidity (35 U.S.C. 102(f)) against any of Gregory's claims. Since Tsui has opposed any change in inventorship, it appears to accede to the adequacy of the status quo. This dismissal does not change that status quo. Moreover, no testimony has been submitted for consideration on this disputed matter. Given the great age of these interferences and the prejudice to the public of any further effective term extension for any resulting patent to resolve the issue would be an exercise in absurdity. Absent a related actively contested issue (e.g., § 102(f) or availability for corroboration), a mistake in inventorship is viewed as easily cured. Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc., 134 F.3d 1085, 1089, 45 USPQ2d 1355, 1359 (Fed. Cir. 1998).

Collin's motion to change inventorship is also dismissed as moot. All of its claims corresponded to the 933 count and those claims are canceled by operation of this judgment.

²⁰ It is not clear why Riordan is not the senior party to Tsui. 37 C.F.R. § 1.601(m). Riordan, however, never raised the issue during the course of the interference. Presumably Riordan had good reason not to raise the issue. We will not further delay the proceeding by raising it sua sponte now.

ORDER

Upon consideration of the preliminary motions of the parties, it is—

ORDERED that 882 Gregory preliminary motion 1 be DENIED;

FURTHER ORDERED that 882 Tsui contingent preliminary motion 1 be DISMISSED as moot;

FURTHER ORDERED that 882 Tsui preliminary motion 2 be DISMISSED as moot;

FURTHER ORDERED that 933 Gregory preliminary motion 1 be GRANTED;

FURTHER ORDERED that 933 Gregory motion to change inventorship be DISMISSED as moot;

FURTHER ORDERED that 933 Collins motion to change inventorship be DISMISSED as moot;

FURTHER ORDERED that 933 Tsui contingent preliminary motion 1 be DENIED;

FURTHER ORDERED that 933 Collins miscellaneous motion to add Tsui applications be DISMISSED as moot;

FURTHER ORDERED that 933 Collins motion to change inventorship be DISMISSED as moot;

FURTHER ORDERED that 228 Gregory preliminary motion 1 be DENIED;

FURTHER ORDERED that 228 Tsui contingent preliminary motion 1 be DISMISSED as moot;

FURTHER ORDERED that Gregory's motions to suppress the Ray declaration are DISMISSED as moot;

FURTHER ORDERED that judgment on priority as to 882 Count 1 is awarded against junior party Gregory;

FURTHER ORDERED that Gregory is not entitled to a patent claiming the subject matter of claims 10-12 of Gregory's 08/311,665 application, which correspond to 882 Count 1;

FURTHER ORDERED that judgment on priority as to 933 Count 1 is awarded against junior party Collins and senior party Tsui;

FURTHER ORDERED that Collins is not entitled to a patent claiming the subject matter of claims 1-16 of Collin's 5,240,846 patent, which correspond to 933 Count 1;

FURTHER ORDERED that Tsui is not entitled to a patent claiming the subject matter of claims 98, 99, and 101-110 of Tsui's 08/252,778 application, which correspond to 933 Count 1;

FURTHER ORDERED that judgment on priority as to 228 Count 1 is awarded against junior party Gregory and junior party Riordan;


FURTHER ORDERED that Gregory is not entitled to a patent claiming the subject matter of claims 1, 3, and 7 of Gregory's 08/470,534 application, which correspond to 228 Count 1;

FURTHER ORDERED that Riordan is not entitled to a patent claiming the subject matter of claims 1-13 of Riordan's 5,543,399 patent, which correspond to 228 Count 1;


FURTHER ORDERED that the preliminary statements be returned; and

FURTHER ORDERED that a copy of this decision be given a paper number and be entered in the administrative records of Gregory's 08/311,665, 08/087,132, and 08/470,534

applications; Tsui's 08/123,864, 08/252,778, and 08/469,630 applications; Collins' 5,240,846 patent; and Riordan's 5,543,399 patent.


RICHARD E. SCHAFER
Administrative Patent Judge


RICHARD TORCZON
Administrative Patent Judge


CAROL A. SPIEGEL
Administrative Patent Judge

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TRIAL SECTION

Interference Nos. 103,882, 103,933, and 104,228
Gregory v. Tsui et al.

Consolidated Judgment
Page 24

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
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The criteria for publication of scientific papers in *Nature* are that they:

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- are of outstanding scientific importance
- are of interest to an interdisciplinary readership.

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Who decides which papers to publish?

Nature has space to publish only 10% or so of the 170 papers submitted each week, hence its selection criteria have to be extremely rigorous.

The judgement about which papers will interest a broad readership is made by *Nature's* editors, not its referees. One reason is because each referee sees only a tiny fraction of the papers submitted, whereas the editors, who see all the papers submitted, can have a broader perspective.

Nature does not employ an editorial board of senior scientists, nor is it affiliated to any particular scientific society or institution, thus avoiding the risk of decisions that are strongly coloured by the scientific or national prejudices of particular board members, as well as reducing the time taken to make decisions.

Because *Nature's* editors judge which papers to publish, decisions are quicker, more uniform across disciplines, and are independent.

What happens to a submitted paper?

Authors intending to submit papers to *Nature* should first refer to the extended guide to authors, most easily seen on the web site at [Guide to Authors](#) where it is also in [PDF format](#), or available from *Nature* direct by request from nature@nature.com. Adherence to this guide will ensure that the level, length and format (particularly the layout of figures and tables) conforms with *Nature's* requirements and will reduce delays in the handling of the paper. The relevant number of papers in press or submitted elsewhere should be included with five copies of the *Nature* submission.

The first hurdle for a newly submitted paper is that the editorial staff consider it to be sufficiently interesting to be sent for peer-review. This judgement is made mainly by the editor most expert on the subject, but informal advice (by phone or email) is taken from regular scientific advisors and papers are discussed among several editorial colleagues to ensure consistency. It is helpful to *Nature's* editors if the paper is accompanied by a cover letter that states briefly why the author thinks the paper belongs in *Nature* rather than in one of the excellent specialist

journals in the field. The initial criteria for a paper to be sent for peer-review are that the results seem novel, arresting (unexpected or surprising), and that the work seems broadly significant outside the field. The initial judgement is not a reflection on the scientific validity of the work described, or on its importance to people in the same field.

Once the editors have decided that a paper is in principle sufficiently interesting to be sent to referees, the choice of referees is usually made by the editor who knows most about the topic in question, and who will be handling other papers in the same field. Most papers are sent to two or three referees, but some are sent to more or, occasionally, just to one. Among the considerations that arise in choosing specific referees are

- whether the referee is independent of the authors and their institutions
- whether the referee can evaluate the technical aspects of the paper fully and fairly
- whether any related papers are under consideration
- whether the potential referee has assessed other papers recently
- whether the referee is available to assess the paper within the requested time.

Referees' reports

The ideal referee's report indicates

- who will be interested in the new results and why
- any technical failings that need to be addressed before the authors' case is established.

Although *Nature's* editors themselves judge whether a paper is likely to interest readers outside its own immediate field, referees often give helpful advice, for example if the work described is not as significant as the editors thought or has perhaps undersold its own significance. Although *Nature's* editors regard it as essential that any technical failings noted by referees are addressed, they are not so strictly bound by referees' opinions as to whether a particular paper belongs in *Nature*.

Nature's editors may also ask referees of submitted Articles whether, in the referee's view, the paper could be condensed to a Letter without loss of essential information.

Competitors

Some of the referees to whom an editor might consider sending a paper may be engaged in competing work that could influence their opinion. To avoid such conflicts of interest, *Nature* requires potential referees to disclose any conflicts or commercial interest before undertaking to review a paper, and requires referees not to copy papers or to circulate them to unnamed colleagues.

Nature welcomes authors' suggestions for suitable independent referees (with their contact details), but editors are free not to use these referees.

Nature honours requests that a paper not be sent to one or two (but no more) competing groups for review, although it is *Nature's* experience that competitors often enthusiastically recommend papers.

Speed

Nature makes decisions about submitted papers as rapidly as possible. Authors are usually informed within a week if the paper is not being considered (authors are not currently informed that their paper has been sent out for review, but they receive an acknowledgement with a reference number which should be cited in all future communication about that paper).

Nature makes every effort to provide rapid delivery of referees' reports. Most referees honour their prior agreement with *Nature* to report on a paper within seven days or other agreed time limit, and most referees send reports by email. Referees are chased by phone, fax or email if they have not delivered their report within the agreed time.

Exceptionally important papers

Of course, every author believes that his or her paper is important, particularly in highly competitive fields, and entitled to the quickest possible handling. *Nature* strives to provide this service for all submitted papers.

In exceptional cases, if the work described in a submitted paper seems to the editors to be so important that it would be considered a privilege to be asked to review it, and if the editors know of competing similar work in press elsewhere, *Nature* can offer a fast-track procedure in which a paper is refereed within 48 hours and is typeset before receipt of the referees' reports in the expectation that major alterations will not be required in the light of the reports. On rare occasions such as these, it is possible to publish a paper within 2 weeks of submission.

Decisions

Once all the referees' reports on a paper have been received, the editor handling the paper writes a summary of the paper's contents and the referees' opinions, a recommendation, and a draft letter to the authors for internal discussion with other editors, including the biology or physical sciences editor. Thus *Nature* ensures that the criteria used by all editors are uniform, and that the paper has received expert assessment.

Once an editorial consensus has been reached, a letter of decision is sent to the authors, generally by fax or email, together with the referees' reports (sent anonymously, unless the referees have explicitly directed otherwise).

What the decision letter means

Letters from *Nature* editors will offer the authors of a paper one of the following options:

- The paper is accepted for publication without any further changes

required from the authors. In practice, this course of action is extremely rare.

- The paper is accepted for publication in principle once the authors have made some revisions in response to the referees' comments. Under these circumstances, revised papers are not usually sent back to the referees for a second opinion, but are accepted for publication once the editors have checked that the referees' suggestions have been implemented.
- A final decision on publication is deferred, pending the authors' response to the referees' comments. Under these circumstances, further experiments are usually required to address some or all of the referees' concerns, and revised papers are sent back to some or all of the referees for a second opinion. Revised papers should be accompanied by a point-by-point response to all the comments made by all the referees.
- The paper is rejected because the referees have raised considerable technical objections and/or the authors' claim has not been adequately established. Under these circumstances, the letter will state explicitly whether or not a resubmitted version would be considered. If the editor has invited the authors to resubmit, authors should ensure that all the referees' comments have been satisfactorily addressed (not just some of them) and should accompany the resubmitted version with a point-by-point response to the referees' comments. Resubmitted papers are sent back to the reviewers only if it seems to the editor handling the paper that the authors have made a serious attempt to address all the referees' criticisms, rather than revising it minimally. (Papers that have been revised only minimally will be returned to the authors without being sent back to the referees.)
- The paper is rejected with no offer to reconsider a resubmitted version. Under these circumstances, authors are strongly advised not to resubmit a revised version as it is likely that it will be returned to them without further review. If the authors feel that they have a strong scientific case for reconsideration (if the referees have missed the point of the paper, for example) they can appeal the decision in writing ([see below](#)). But in view of *Nature's* extreme space constraints and the large number of active papers under consideration at any one time, editors cannot assign a high priority to consideration of such appeals.

Note that very few papers are published without significant revisions to the original submission. Some of the papers of which *Nature* is most proud of publishing are those which were originally weak but intriguing, and have become really striking only by virtue of extensive attention from the referees and editors.

Editors' letters also contain detailed guidance about the paper's format and style ([see below](#)).

Revising papers

In replying to the referees' comments, authors are advised to use language that would not cause offence when their paper is shown again to the

referees, and to bear in mind that if a point was not clear to the referees and/or editors, it is unlikely that it would be clear to the nonspecialist reader.

Authors should refer to the [guide to authors](#) once again when revising their paper and figures for publication, and ensure that the correct number of copies are included.

Appeals

If *Nature* declines to publish a paper and does not suggest resubmission, authors are strongly advised to submit their paper for publication elsewhere. If an author wishes to appeal against *Nature*'s decision, the appeal must be made in writing, not by telephone, and should be confined to the scientific case for publication. *Nature*'s editors are unable to assign high priority to consideration of appeals.

One common complaint by authors of rejected papers is that *Nature* has chosen inappropriate referees. These authors ask for the referees' advice to be disregarded, and often suggest the names of "real experts" in the field. Surprisingly often, one or more of the individuals named by the authors is already a referee of the paper.

In any event, *Nature* prefers to stick with the views of the original referees of a particular paper rather than to call in new referees to arbitrate, unless there is some specific reason why a referee can be shown to be biased that was previously unclear to the editors. If *Nature*'s editors agree to reconsider a particular paper, the other referee(s) will have the chance to see and comment on the report of the referee who is the subject of the complaint.

If an author remains unsatisfied with *Nature*'s answer to an appeal, he or she can write again to the biological or physical sciences editor or, if the author is still unsatisfied, to the Editor. In all these cases, it is likely that some time will elapse before *Nature* can respond.

Formats and lengths of papers

Once *Nature*'s editors have agreed on scientific grounds to accept a paper in principle for publication, they examine the paper's format in detail.

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Nature's editors will sometimes set a length limit of greater or less than 2.5 pages for a particular Letter (or greater or less than 5 pages for a particular Article). These decisions are made after careful consideration and discussion of individual papers. When *Nature* asks for significant reductions in length, the editor will make specific suggestions for the required shortening. Many authors are pleasantly surprised to find how easy it can be to condense text by focusing on the really essential points. The result of this exercise is a paper that is easier to read and understand, and hence one that will be more widely cited and influential.

If an author has not provided a revised paper at or around the length requested by the editor, it may be returned to the author for further shortening, with resultant further delay. Revised papers that are only a small amount over length may sometimes be reduced by the editors. But authors are best placed to prepare the paper at the requested length to ensure that there are no unintentional distortions to the meaning introduced during shortening.

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Nature's subeditors are happy to advise authors about the format of their papers. Their role is to

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- ensure that the paper is at the length specified by the manuscript editor
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- ensure that the figures and tables are clear and will fit in the space available.

Preparation of the paper

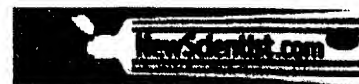
In preparing the final version of the paper, authors should refer again to the guide to authors. Points worth emphasizing are:

- The introductory paragraph of Letters. This is a single, fully referenced paragraph of no more than 180 words (ideally shorter) which should both introduce the work and provide a non-technical summary. The composition of these paragraphs is relatively difficult; *Nature's* editors and subeditors are willing to help in rewriting the authors' material if requested.
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- Reference lists should contain the titles of books and articles cited.
- Methods sections of not more than 800 words long are placed at the end

of the text. Figure legends do not contain methods unless each legend is shorter than 100 words.



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A single paragraph of fewer than 120 words. References should not be cited in the Summary.

Running Title

No more than 50 characters (including spaces).

Introduction

Succinct, with no subheadings.

Results and Discussion

These sections may each be divided by subheadings or may be combined. *Footnotes should not be used and will be transferred to the text.* Gene symbols should be italicized; protein products are not italicized. Nonstandard abbreviations should be defined when first used in the text. All text should be letter quality and double spaced.

Experimental Procedures

This section should contain sufficient detail so that all procedures can be repeated, in conjunction with cited references.

References

The references include only articles that are published or in press. Unpublished data, submitted manuscripts, abstracts, and personal communications should be cited within the text only. Personal communication should be documented by a letter of permission. Please use the following style for references:

Article in a periodical:

Sondheimer, N., and Lindquist, S. (2000). Rnq1: an epigenetic modifier of protein function in yeast. *Mol. Cell*, 163–172.

Article in a book:

Sorenson, P.W., and Caprio, J.C. (1998). Chemoreception. In *The Physiology of Fishes*, D.H. Evans, ed. (Boca Raton, FL: CRC Press), pp. 375–405.

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Cowan, W.M., Jessell, T.M., and Zipursky, S.L. (1997). *Molecular and Cellular Approaches to Neural Development* (New York: Oxford University Press).

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Each copy of a submitted manuscript should be provided with a set of figures of sufficient quality for reviewers to judge the data. Multipane figures should be premounted as a montage ready for scanning. Magnification should be indicated by a bar scale. Color figures will be included only when in the reviewers' opinions they are essential. Authors will be charged \$1000 for the first and \$100 for each additional color figure, which partially defrays the cost of separating and printing color figures. There are no page charges.

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A minireview discusses briefly a sharply focused topic of recent experimental research and makes it accessible to researchers in other areas: should direct the reader to a few (no more than 20) key papers in the field, which come under the heading "Selected Reading." Personal communications and submitted manuscripts should not be cited. A minireview should provide a critical but balanced view of the field. Proposals for minireviews may be submitted to the Senior Editors.

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